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WITNESS my hand this  
Twenty-fourth day of November 2004

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LEANNE MYNOTT  
MANAGER EXAMINATION SUPPORT  
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**AUSTRALIA**

**PATENTS ACT 1990**

**PROVISIONAL SPECIFICATION**

***FOR THE INVENTION ENTITLED:-***

**A Gauge for use in a Surgical Procedure**

**The invention is described in the following statement:-**

**Field of the Invention**

The present invention relates to surgical implements and surgical methods and in particular to a gauge for use in surgical procedures, for example surgery involving prosthetic components.

- 5 The invention has been developed primarily for use in implanting prosthetic components in osteotomological surgery on either humans or animals, for example in relation to hip replacement surgery and the like. However it will be appreciated that the invention is not limited to this particular field of use.

**Background Art**

- 10 Prior art prosthetic implant techniques have typically required the surgeon to align prosthetic components by eye. Use of this prior art technique in hip replacement surgery, for example, may result in misalignment of prosthetic components such as femoral stems and acetabular cups. This misalignment may lead to post operative complications such as misalignment of the leg, incorrect leg length and/or incorrect soft
- 15 tissue tension. The long term effects of misaligned prosthetic components can also include accelerated wear of the components, aseptic loosening of the components and potentially early repetition of the surgery.

- Some of these issues are at least partially addressed by the arrangement disclosed in co-pending patent application No. PCT/AU02/01482 (WO03/037192) the contents of which
- 20 are hereby incorporated in their entirety by reference. This patent specification discloses the use of an alignment handle as shown in figures 20 to 24 and figure 36. This alignment handle has a gauge adapted to indicate whether a prosthetic component is in a

predefined orientation. This alignment handle, whilst a significant improvement over the prior art, nevertheless exhibits certain limitations.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common  
5 general knowledge in the field.

### **Summary of the Invention**

According to a first aspect of the invention there is provided a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane, said gauge including:

10 a body; and

a plumb bob mounted to said body so as to hang under the influence of a local gravitational field, said plumb bob being rotatable relative to said body in both said first plane and said second plane so as to determine said first angle and said second angle respectively.

15 Preferably a universal joint rotatably mounts the plumb bob to the body. In a preferred embodiment the universal joint is a ball joint, however it will be appreciated that other types of universal joints, such as an eye end joint, a tie rod end joint or a rose joint, for example, may be utilised in alternative preferred embodiments.

Preferably the first plane is orthogonal to the second plane.

20 The plumb bob of a preferred embodiment includes a pointer and the body preferably includes markings disposed adjacent the pointer. More preferably, a first sub-set of the

markings corresponds to angular increments of the first angle and a second sub-set of the markings corresponds to angular increments of the second angle.

A preferred embodiment of the invention includes a connector disposed on the body for connection of the gauge to a prosthetic component. An alternative preferred

- 5 embodiment includes a connector disposed on the body for connection of the gauge to a predefined site of a patient.

A preferred embodiment is particularly suited for surgical applications such as the insertion of an acetabular cup into a reamed acetabulum during hip replacement surgery.

- For this application the first angle preferably corresponds to an aversion of the  
10 acetabular cup and the second angle preferably corresponds to an abduction of the acetabular cup.

According to a second aspect of the invention there is provided a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane, said gauge including:

- 15 a body;  
a first plumb bob mounted to said body so as to hang under the influence of a local gravitational field, said first plumb bob being rotatable relative to said body in said first plane so as to determine said first angle; and  
a second plumb bob mounted to said body so as to hang under the influence of a  
20 local gravitational field, said second plumb bob being rotatable relative to said body in said second plane so as to determine said second angle.

Preferably the first plumb bob is mounted to the body for rotation about a first axis and the second plumb bob is mounted to the body for rotation about a second axis, whereby the first axis is orthogonal to the second axis.

A preferred embodiment will now be described, by way of example only, with reference  
5 to the accompanying drawings in which:

Figure 1 is a perspective view of a first preferred embodiment of the invention;

Figure 2 is a plan view of the first embodiment;

Figure 3 is a side view of the first embodiment;

Figure 4 is a rear view of the first embodiment;

10 Figure 5 is a perspective view of a second preferred embodiment of the invention;

Figure 6 is a plan view of the second embodiment;

Figure 7 is a side view of the second embodiment;

Figure 8 is a rear view of the second embodiment;

Figure 9 is a perspective view of a plumb bob as used in both the first and second  
15 preferred embodiments of the invention;

Figure 10 is a side view of the plumb bob shown in figure 9;

Figure 11 is a rear view of the plumb bob shown in figure 9;

Figure 12 is a plan view of the plumb bob shown in figure 9;

Figures 13 and 14 are plan views of respective left and right cup holders;

20 Figure 15 is a plan view of a handle assembly;

Figures 16 and 17 are side and plan views respectively of an alignment frame;

Figures 18 and 19 are plan views of spacer members for operating on a left and  
right hip respectively;

Figure 20 is a perspective view of a patient immediately prior to commencement  
25 of hip replacement surgery;

Figure 21 is a perspective view showing part of a spacer alignment tool being applied to a patient's acetabulum; and

Figure 22 is a plan view of a read-out face of a third preferred embodiment of the invention.

- 5 Referring to the drawings, the first preferred embodiment of the gauge 1 includes a body 2 with a plumb bob 3 mounted to the body 2. The plumb bob 3 hangs from the body 2 under the influence of a local gravitational field. More particularly, the plumb bob 3 is rotatable relative to the body 2 in both a first plane denoted by dotted line 4 in figure 2 and a second plane denoted by dotted line 5 also shown in figure 2. The first plane is  
10 orthogonal to the second plane.

A universal joint, in the form of ball joint 6, rotatably mounts the plumb bob 3 to the body 2. The universal joint 6 has a ball 7 which is centrally housed within the plumb bob 3. An internal surface 8 of the plumb bob 3 has a convex shape which conforms to the concave surface of the ball 7. An axle 9 extends through the center of the ball 7 to  
15 define first and second cylindrical ends 10 and 11. Along conical sections 12 and 13 the radius of the axle 9 increases from that of the thin central part which is embedded within the ball 7 to that of the larger first and second cylindrical ends 10 and 11. The axle 9 extends through apertures 14 and 15 provided in the plumb bob. The apertures 14 and 15 define annular stops 16 and 17 respectively. The ball 7 is free to move in any  
20 direction relative to the plumb bob 3, at least until the point at which either of the conical sections 12 or 13 impacts upon the adjacent annular stop 16 or 17. The range of movement of the plumb bob 3 relative to the axle 9 is extended by the arcuate wasting of the side walls of the plumb bob 3 in the regions of the apertures 14 and 15, as best shown in figure 11.

- To assemble the plumb bob and axle, the ball 7, plumb bob 3 and axle components are firstly fabricated separately. The plumb bob 3 is initially hollow in the region immediately below the housing for the ball 7. This allows the ball 7 to be inserted through the aperture 20 in the base 21 of the plumb bob 3. The ball 7 is then sealed
- 5 inside the plumb bob 3 by core 19 which is inserted through aperture 20 and which then fills the hollow immediately below the ball 7. The thin part of the axle 9, with the first cylindrical end 10 attached, is then threaded through aperture 15 and an aperture provided in the ball 7. Finally, the second cylindrical end 11 is secured to the other side of the thin part of the axle 9 by fastener 22.
- 10 The plumb bob 3 is then mounted to the body 2 by fixedly connecting the cylindrical ends 10 and 11 to the body 2, as best shown in figure 2.

The body 2 includes a semi-circular opening 28 which provides clearance for the base 21 of the plumb bob 3 to assume different positions under the influence of gravity as the orientation of the gauge 1 is changed relative to a local gravitational field. To assist with

15 weight reduction, a number of apertures 39 may be provided in the body 2, as shown for example in figures 3 and 7.

In use, the body 2 is oriented relative to the plumb bob 3 such that the conical sections 12 and 13 are not in contact with the annular stops 16 and 17. This, combined with the fact that the plumb bob 3 has a center of gravity 18 which is lower than the pivot point

20 defined by the ball 7, ensures that the plumb bob 3 is free to hang vertically due to its weight.

In alternative embodiments (not illustrated) the universal joint 6 takes other forms, for example an eye end joint, a tie rod end joint or a rose joint.



The plumb bob 3 has a pointer 23 which extends above the universal joint 6. When free to hang from the ball joint 7 under the influence of gravity, the end of the pointer 23 is positioned directly above the center of the ball joint 6 and the center of gravity 18 of the plumb bob 3 is positioned directly below the center of the ball joint 6. The body 2 defines a chamber 29 which provides clearance for movement of the pointer 23.

The upper surface of the body 2 includes markings 24, 25, 26 and 27 disposed adjacent the pointer 23. A first sub-set 24 and 26 of the markings corresponds to angular increments of the first angle and a second sub-set 25 and 27 of the markings corresponds to angular increments of the second angle. In this way the gauge 1 may be used to determine a first angle in the first plane 4 and a second angle in the second plane 5. For example in one preferred embodiment, the markings 24 and 26 correspond to 5° increments of the first angle ranging from -25° at one extremity of the markings, through 0° at the center of the markings, and out to +25° at the opposite extremity of the markings. Similarly, the markings 25 and 27 correspond to 5° increments of the second angle ranging from -10° at one extremity of the markings, through 0° at the center of the markings, and out to +10° at the opposite extremity of the markings. In use, the surgeon, or other person using the preferred embodiment, can assess the position of the tip of the pointer 23 relative to markings 24 or 26 to determine the first angle. The user can also assess the position of the tip of the pointer 23 relative to markings 25 or 27 to determine the second angle. Hence, the one surgical implement advantageously allows the user to quickly and simply determine two separate angles associated with the orientation of the gauge 1 relative to a local gravitational field.

The gauge 1 of the present invention is preferably replaces the alignment handle 158 shown in figure 36 of co-pending PCT Application No. PCT/AU02/01482 (WO03/037192).

A connector 30 is disposed on the body 2 for connection of the gauge 1 to a prosthetic component, or to another surgical implement, or to a predefined site of a patient. For example, the gauge 1 may form one component of a surgical implement, for example a cup alignment tool which comprises:

- the gauge 1;
- either the left or right cup holder 158 as shown in figures 13 and 14 respectively;
- and
- the handle 213 shown in figure 15.

The body 2 of the gauge 1 defines a distal end 31 and a proximal end 32, with a handle 34 intermediate the ends. The plumb bob 3 is disposed adjacent the proximal end 32. A connector, which includes an internally threaded collar 30, is disposed at the distal end 31. Assembly of the cup alignment tool requires mating of the collar 30 with either of the cup holders 158 shown in figures 13 and 14. The appropriate cup holder 158 is attached to the gauge 1 via attachment means 160 disposed on a proximal end 164 of the cup holder 158. More particularly, the attachment means 160 includes a projection 169 which keys into the connector on the distal end 31 of the gauge 1 to ensure correct relative alignment between the two components. Once keyed into each other, the internally threaded collar 30 engages the external thread 224 on the cup holder 158 to secure the two components together.

The handle 213 show in figure 15 provides the surgeon with additional leverage when manipulating the cup alignment tool 167. To connect the handle 213 to the cup holder

158, an external thread 163 on the handle 213 threadedly engages an internal thread 162 disposed within the cup holder 158. The resulting cup alignment tool 167 is similar to that illustrated in figure 69 of co-pending PCT Application No. PCT/AU02/01482 (WO03/037192), although with the alignment handle 159 replaced by the gauge 1.

- 5 The next step is to attach a prosthetic acetabular cup of appropriate size onto the cup alignment tool (with one or more spacers if required to match the size of the prosthetic acetabular cup). The surgeon then manipulates the cup alignment tool into the wound such that the cup is adjacent the reamed acetabulum.

It is now necessary to orient the cup alignment tool to ensure that the prosthetic  
10 acetabular cup is in an anatomically correct orientation for insertion into the reamed acetabulum. This is achieved with reference to the two angles indicated by the pointer 23 on the gauge 1 in combination with an alignment frame 176 as shown in figures 16 and 17. In other words, the cup alignment tool may be utilised by the surgeon in a manner similar to that described in co-pending PCT Application No. PCT/AU02/01482  
15 (WO03/037192), however with the added benefit of the extra information provided to the surgeon by monitoring two angles in two different planes with the present gauge 1 rather than a single angle in a single plane as indicated by the plumb bob 173 of the alignment handle 159 disclosed in co-pending PCT Application No. PCT/AU02/01482 (WO03/037192). The geometry of the connector 158 relative to the gauge 1 and the  
20 orientation of the patient (which is maintained in a stable condition using the pelvic holder 230 shown in figure 20) is such that the first angle in the first plane read with reference to markings 24 or 26 corresponds to an aversion of the acetabular cup relative to the reamed acetabulum. Similarly, the second angle in the second plane read with

reference to markings 25 or 27 corresponds to an abduction of the acetabular cup relative to the reamed acetabulum.

The alignment frame 176 shown in figures 16 and 17 may be used to accurately align the acetabular cup in a plane other than those indicated by the plumb bob 3. The alignment  
5 frame 176 includes a frame member 177 which defines a first end 178 and a second end 179. The frame member 177 is generally 'L' shaped when viewed from the side, and 'A' shaped when viewed in plan. An abutment pad 180 is disposed on the first end 178 and is adapted to abut a planar surface, in particular the vertical side of the operating table. For example, the surgeon may use his or her knee to press the abutment pad 180  
10 against the side of the operating table. The second end 179 of the alignment frame 176 is positioned adjacent the patient's hip.

Engagement means in the form of a slotted member 181 is disposed on the second end 179 and is aligned so as to project toward the patient's hip. The open-ended slot 225 in the slotted member 181 defines a semi circular surface 226 having an internal radius of  
15 curvature which matches an external radius of curvature of the handle 34 of the gauge 1. In other words, the slot 225 is sized so as to receive and direct the handle 34. The geometry is such that engagement of the handle 34 with the engagement means 181 forces the alignment handle 159 into a predefined orientation with respect to a third plane which is different to the two planes associated with the plumb bob 3. This is  
20 because the slotted member 181 has a width 227 sufficient to ensure that when the handle 34 is engaged with the slotted member 181, the longitudinal axis of the handle 34 matches the axis of the slotted member 181. More particularly, when the handle 34 is disposed within the slotted member 181, the handle 34, and therefore the gauge 1, is substantially perpendicular to the side of the operating table. Whilst in this position, the

surgeon can tilt the gauge 1 to adjust the aversion and rotate the gauge 1 to adjust the abduction.

Hence, when each of the following conditions are met:

- 5       • the patient's hip is in the predefined position on the operating table as shown in figure 20;
- the first end 178 of the alignment frame 176 is abutted against the side of the operating table adjacent the patient's hip so that the slotted member 181 faces the patient's hip;
- the handle 34 of the gauge 1 is engaged with the slotted member 181; and
- 10     • the pointer 23 of the gauge is indicating the desired angles for the aversion and the abduction,

then the surgeon can be confident that the prosthetic acetabular cup is correctly positioned for insertion into the patient's hip. At this point the surgeon utilises a punch assembly to impact the acetabular cup into the reamed acetabulum.

- 15   Another step in a typical hip replacement operation is insertion of a stem into the femoral canal. After insertion, an end 34 of the stem 33 projects from the end of the femur. It is now necessary to determine the prosthetic neck length required for post operative correct leg length, tissue tension and muscle tension. A short trial head is placed onto the stem and the hip joint is reduced. As best shown in figure 21, a spacer
- 20   alignment tool 189 is assembled by connecting a left or right spacer member 190, as required, to the gauge 1 in a similar manner to the way in which the cup holder 158 was previously attached to the gauge 1. That is, the projection 191 keys into an aperture

disposed in the connector 30 on the distal end 31 of the gauge 1. The collar 30 threadedly engages the proximal end 192 of the spacer member 190. Also similar to the previous assembly of the cup alignment tool, the handle 213 is screwed into the spacer member 190 at internal thread 193 provided adjacent the proximal end 192 of the spacer member 190. In other words, to assemble the spacer alignment tool 189, simply start with the cup alignment tool and replace the cup holder 158 with the spacer member 190.

The spacer member 190 includes a spacer 194 which has a slot 195 adapted to engage an end 34 of the prosthetic stem which has been inserted into the femoral canal. This positions the spacer 194 intermediate the trial head and the end 34 of the femur, as shown in figure 21 (although the trial head is obscured within the reamed acetabulum). When properly positioned, the trial head is disposed within the hemispherical surface 203. Once again the surgeon may make use of the plumb bob 3 on the gauge 1 in combination with the alignment frame 176 to ensure that the spacer 194 and the trial head are oriented in an anatomically correct manner whilst performing tests to determine an appropriate prosthetic neck length.

Another exemplary application for the gauge 1 is measurement of the natural geometry of a patient prior to insertion of prosthetic components. For example, once a hip joint has been dislocated, a surgeon may wish to measure the naturally occurring aversion and abduction angles of a patient's acetabulum. For such an application the gauge 1 is connected to a connector which is abutted against the patient's acetabulum and the gauge is maintained in a predefined relationship relative to the patient (for example by means of a pelvic holder 230 as shown in figure 20 and an alignment frame as shown in figures 16 and 17 in a similar manner to that described above). This allows the surgeon to determine the natural aversion angle from the markings 24 or 26 and the natural

abduction angle from the markings 25 or 27. These figures are then noted for subsequent use, for example the surgeon may choose to insert the prosthetic acetabulum at the same aversion and abduction angles as the natural angles determined above.

The alternative preferred embodiment of the gauge 37 shown in figures 5 to 8 is substantially identical to the preferred embodiment of the gauge shown in figures 1 to 4, however with the exception of the provision of a different connector 30 which is in the form of a clamp. This clamp includes a lug 35 fixedly disposed opposite an end 36 of a bolt 37. Hence, part of an object to which the gauge 37 is to be connected may be placed intermediate the lug 35 and the bolt end 36. The bolt head 38 is then rotated so as to screw the bolt end 36 toward the lug 35, thereby clamping the gauge 37 to the object.

Another embodiment of a gauge 40 includes a read-out face as illustrated in figure 22. This embodiment differs from the above embodiments in that it utilises two separate plumb bobs 41 and 42 as opposed to a single plumb bob 3. In such an embodiment, the first and second plumb bobs 41 and 42 are separately mounted to the gauge body 43 so as to each hang under the influence of gravity. The first plumb bob 41 is mounted to the body 43 for rotation in the first plane about a first axis 44 and the second plumb bob 42 is mounted to the body 43 for rotation in the second plane about a second axis 45. The first axis 44 is orthogonal to the second axis 45. In use, the surgeon compares the position of the first plumb bob 41 against either markings 46 or 47 to determine the first angle. Similarly, the position of the second plumb bob 42 is compared against markings 48 or 49 to determine the second angle. This embodiment has the advantage of mechanical simplicity in comparison to gauges 1 and 37 as illustrated in figures 1 to 8 since this embodiment does not require the provision of a universal joint 30.

Although the invention has been described with reference to specific embodiments, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

DATED this 12<sup>th</sup> day of November 2003

5 BALDWIN SHELSTON WATERS

Attorneys for: International Patent Owners (Cayman) Limited



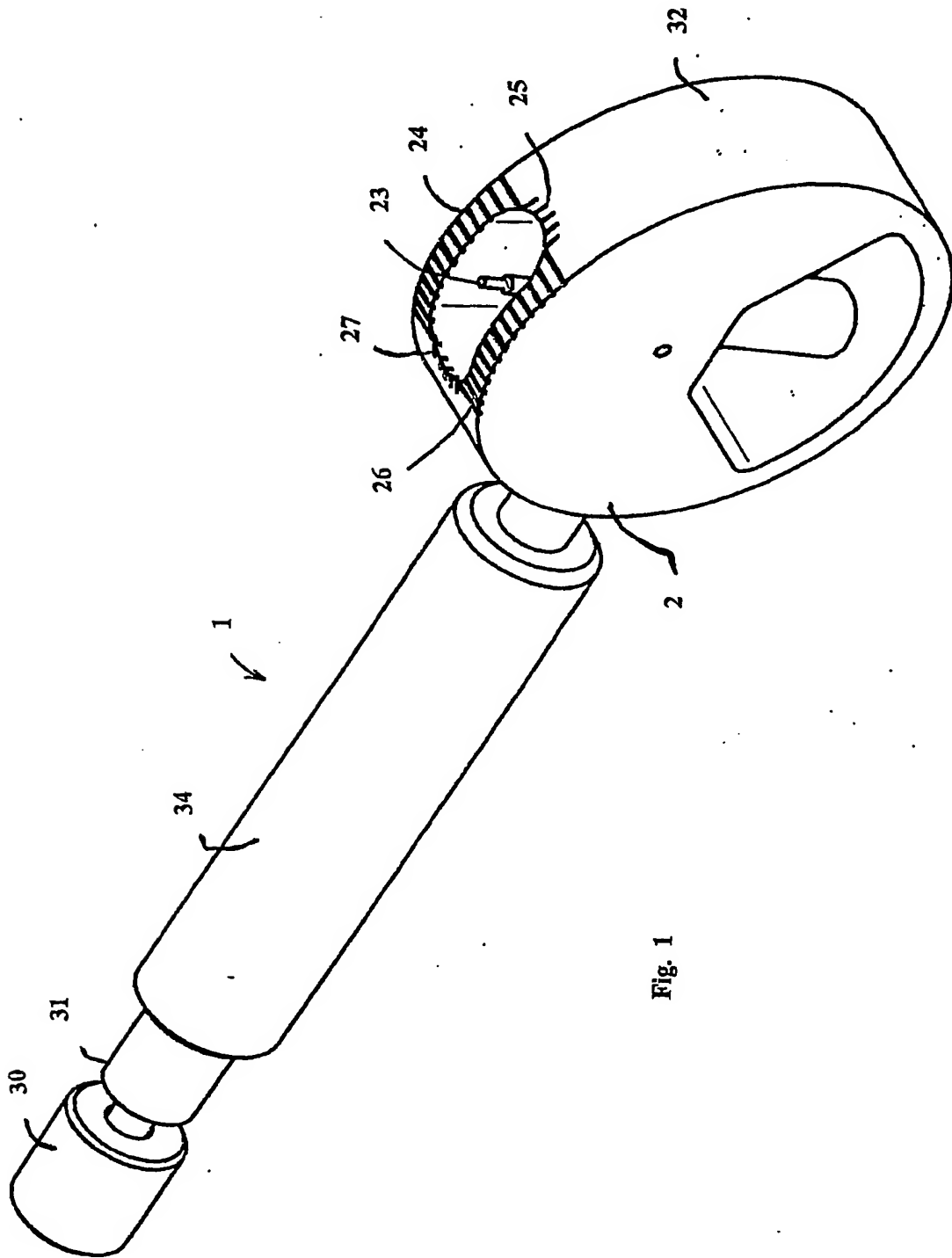
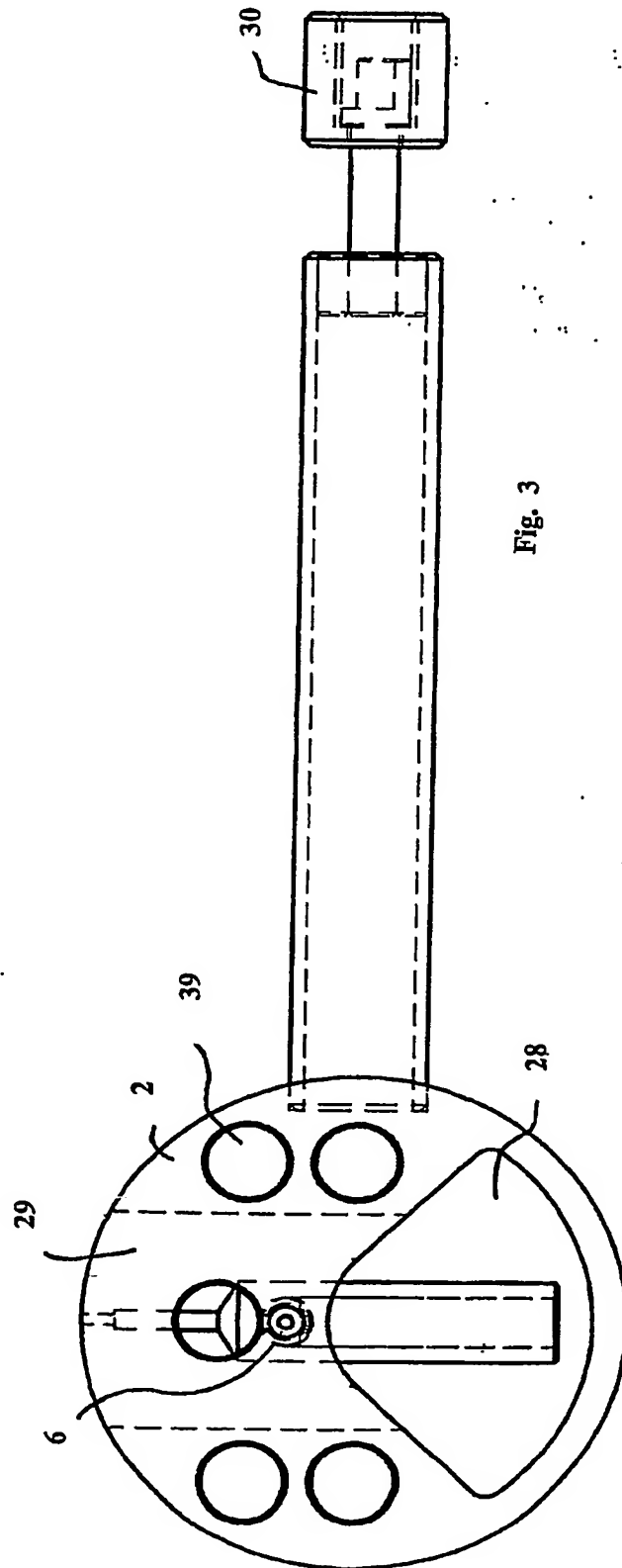
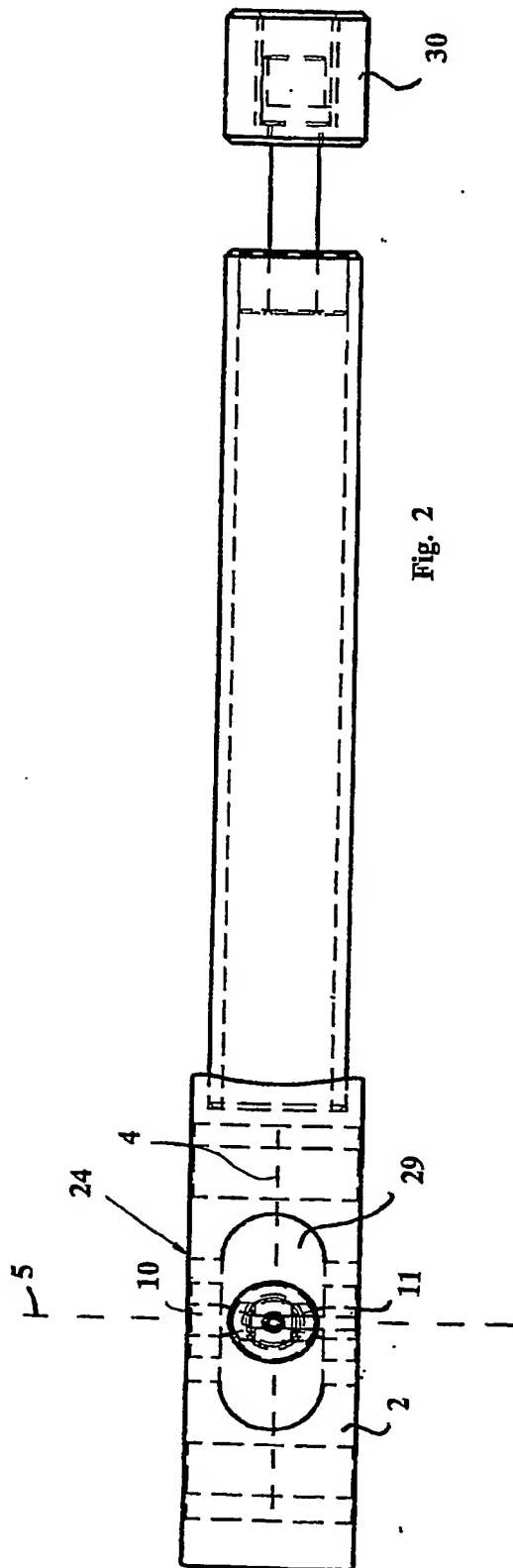


Fig. 1



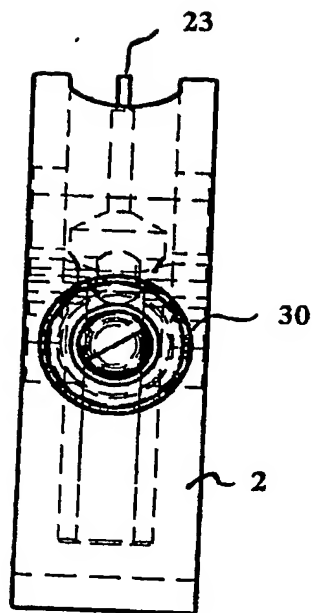


Fig. 4

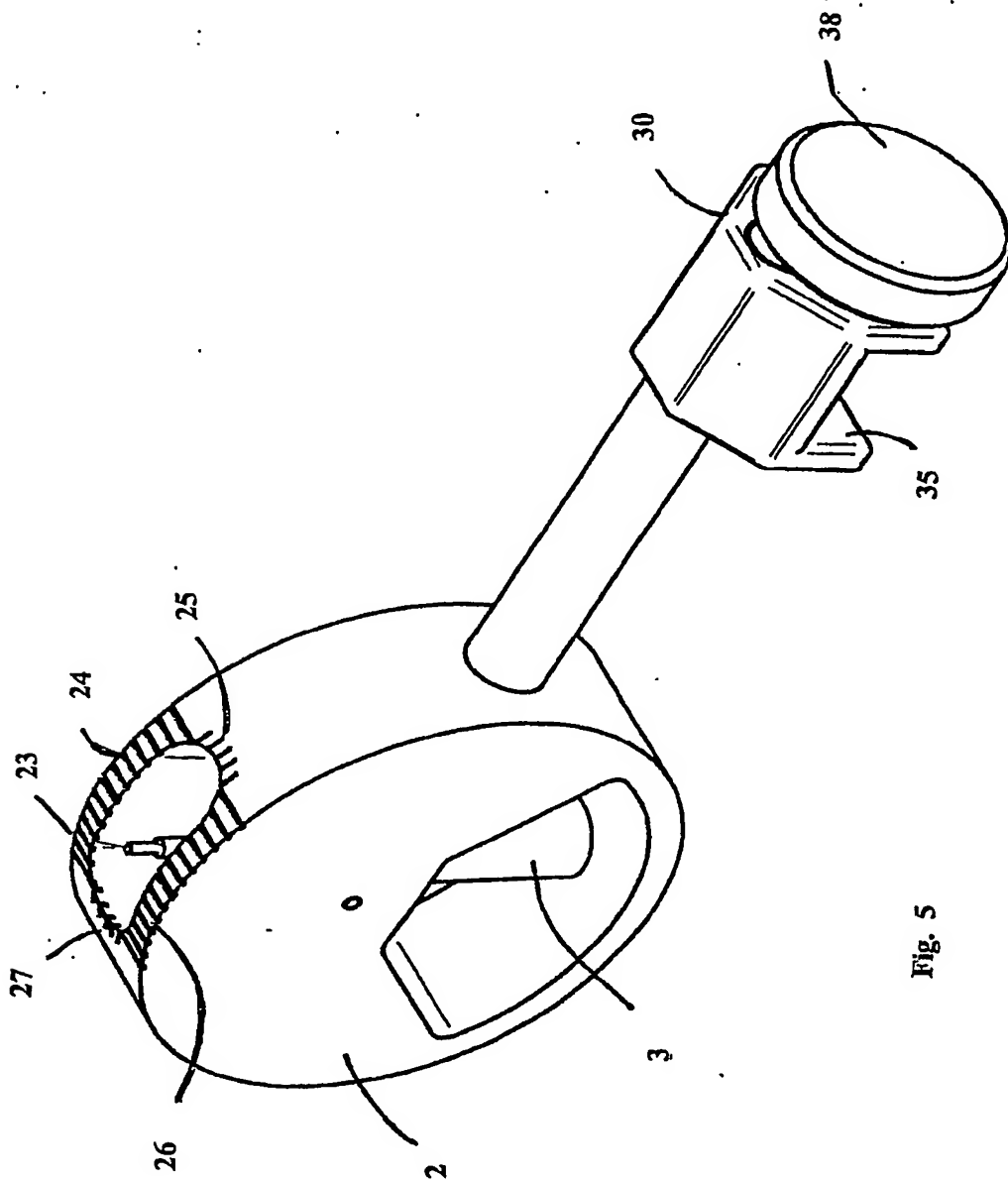


Fig. 5

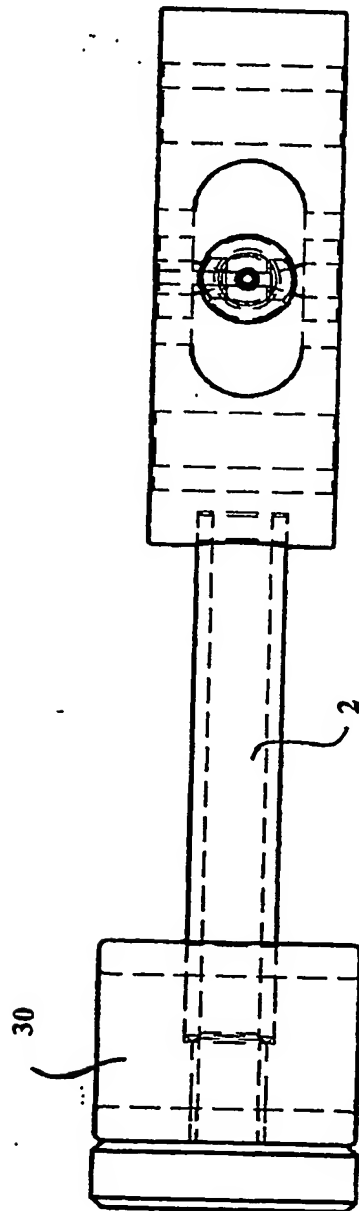


Fig. 6

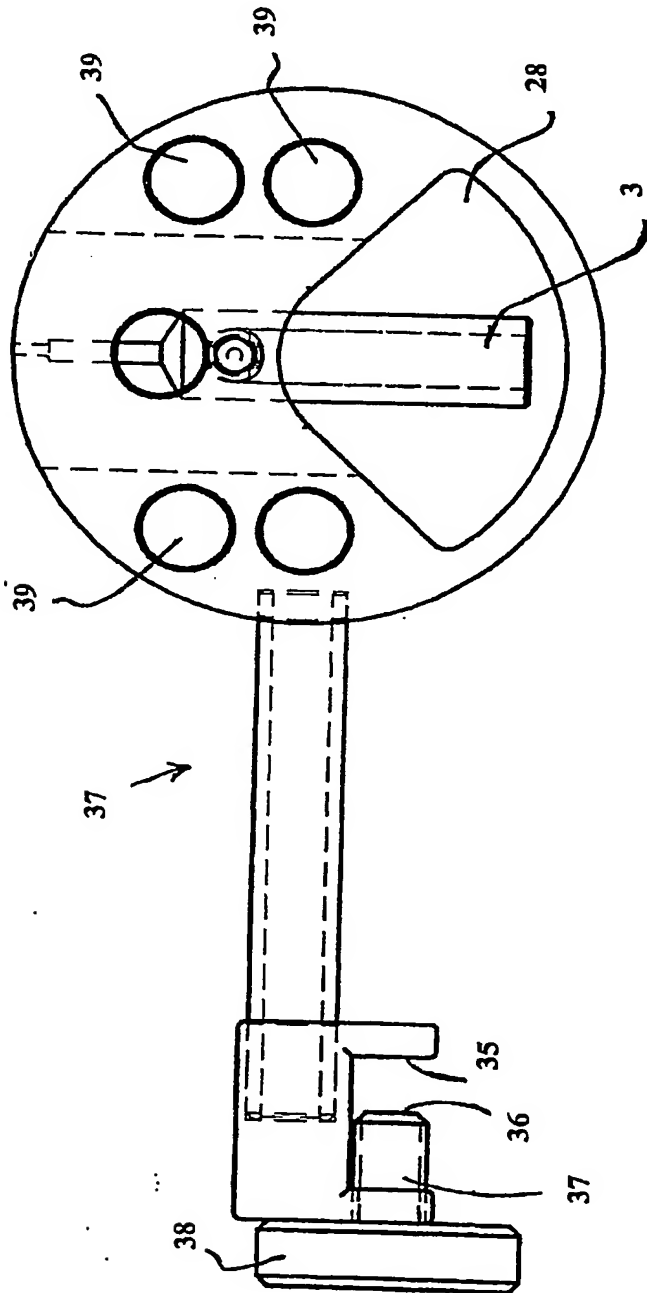


Fig. 7

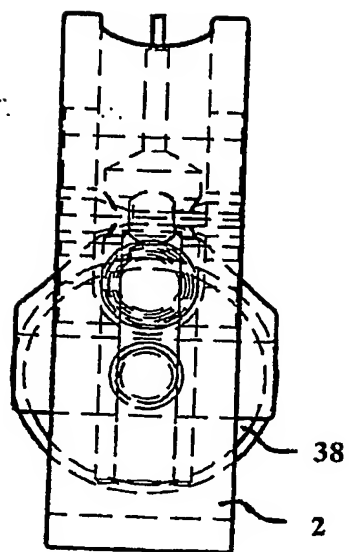


Fig. 8

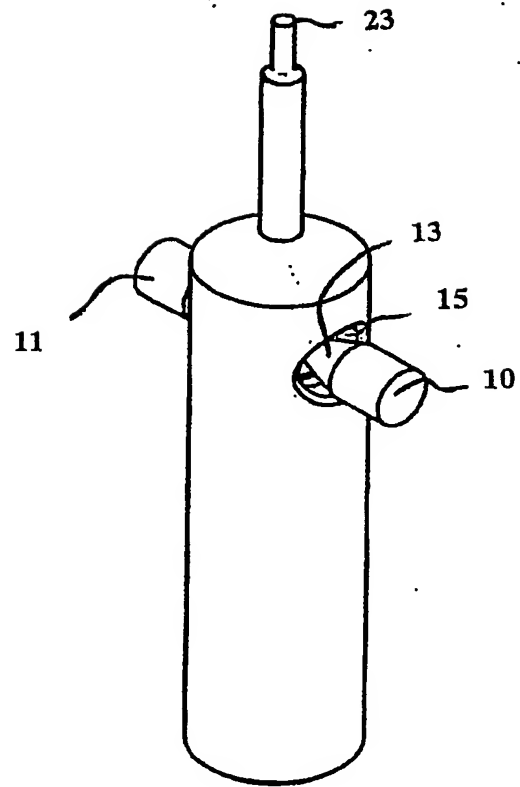


Fig. 9

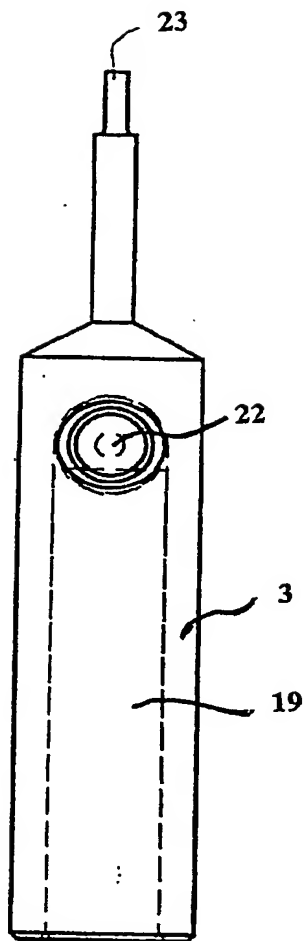


Fig. 10



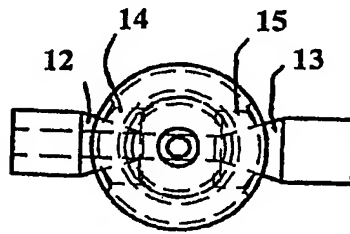


Fig. 12

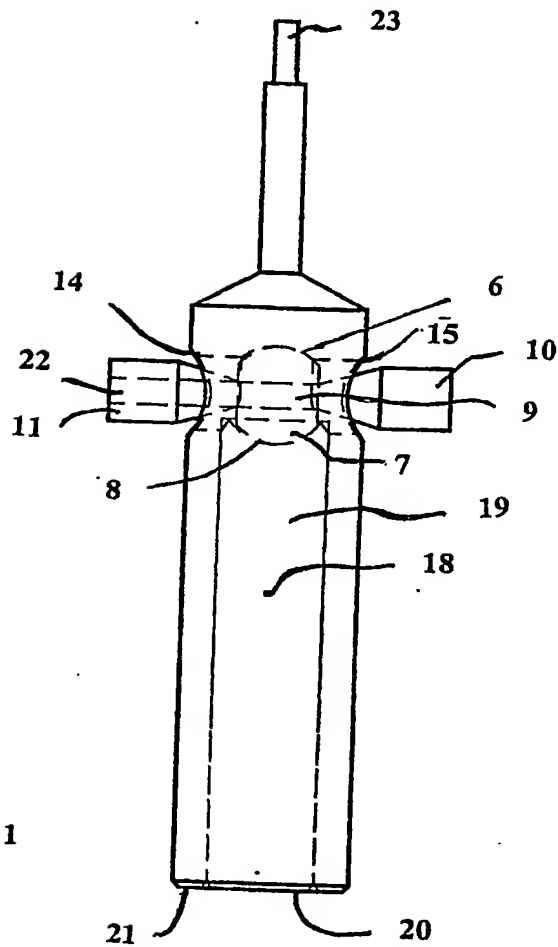


Fig. 11

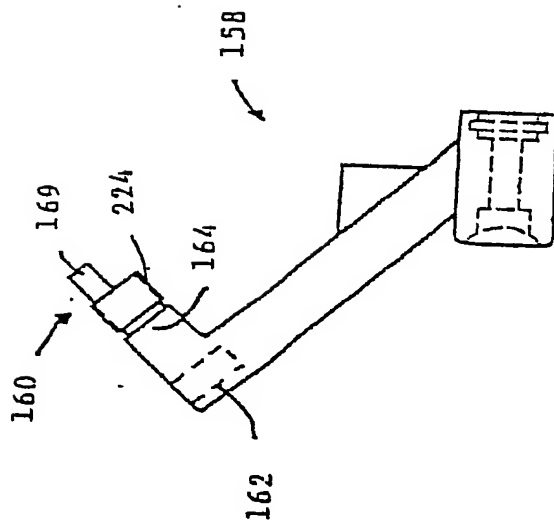


Fig. 13

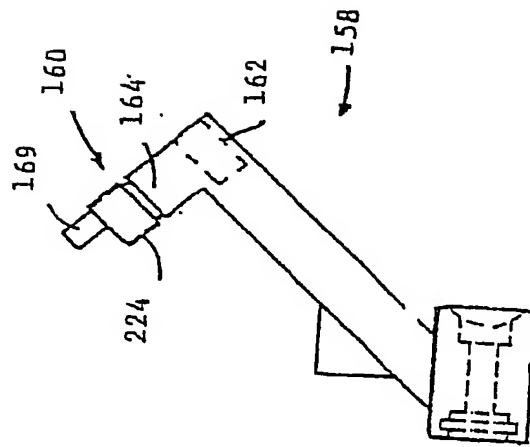


Fig. 14

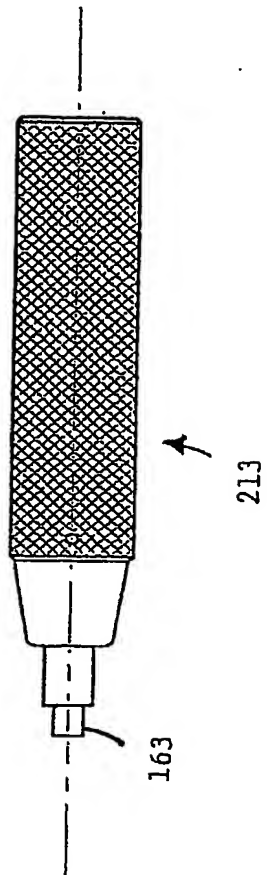


Fig. 15

Fig. 16

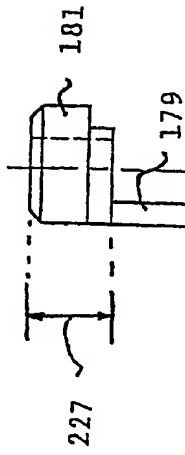


Fig. 17

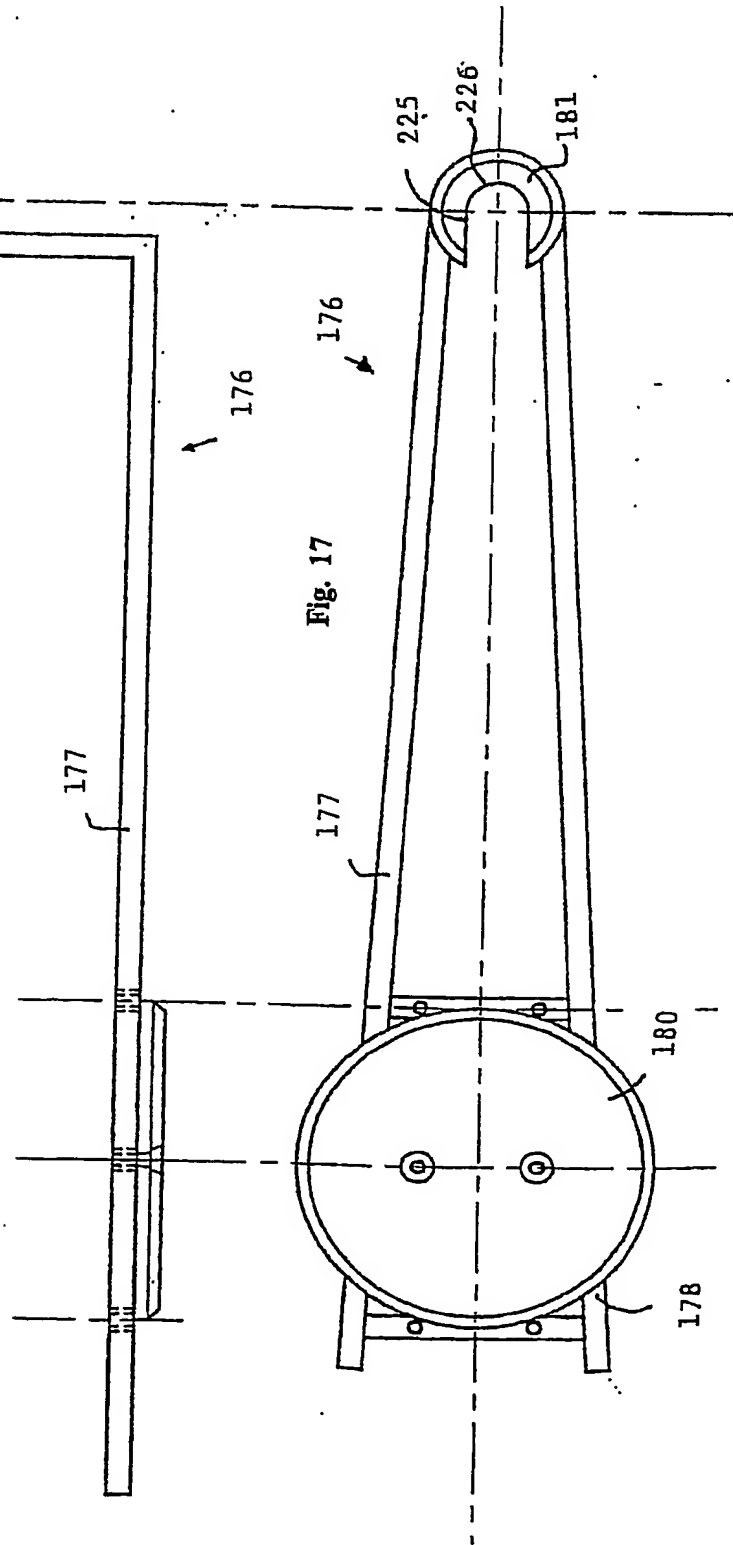


Fig. 18

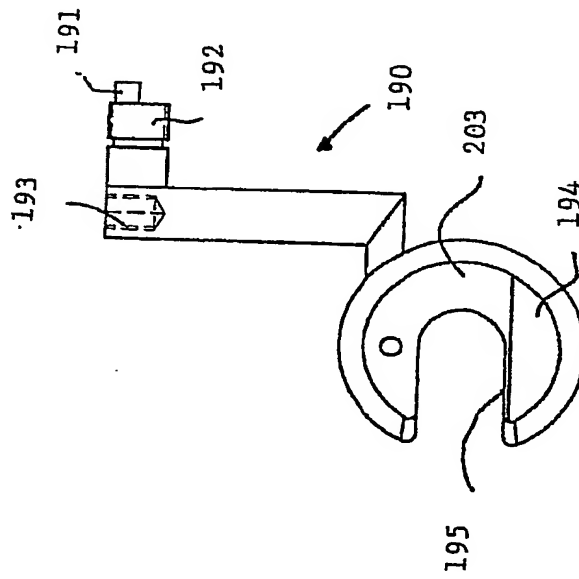
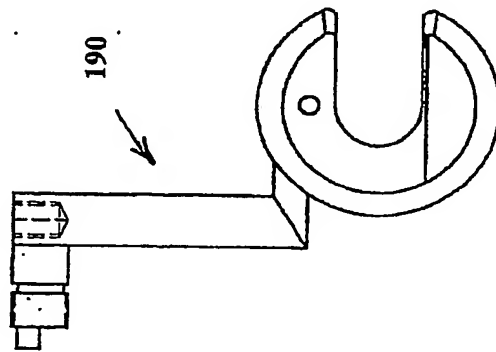


Fig. 19



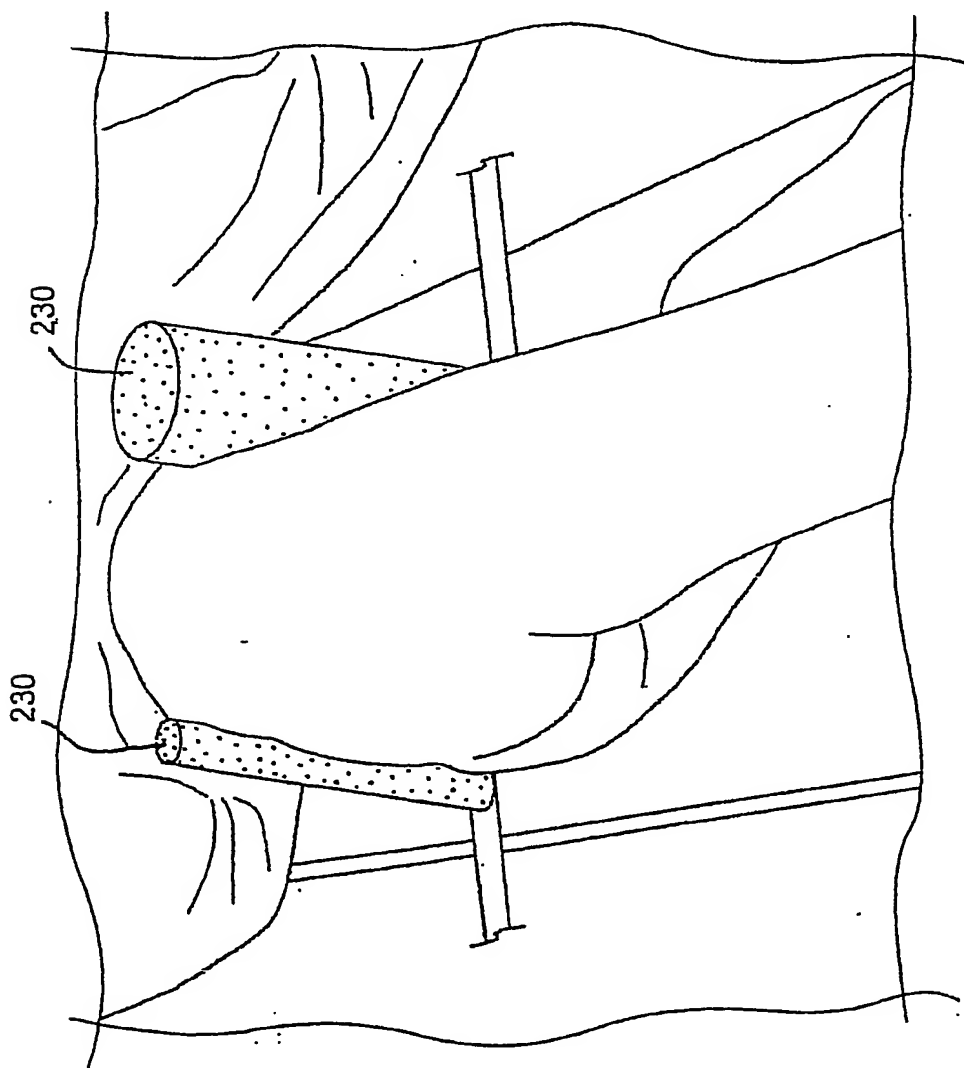


Fig. 20



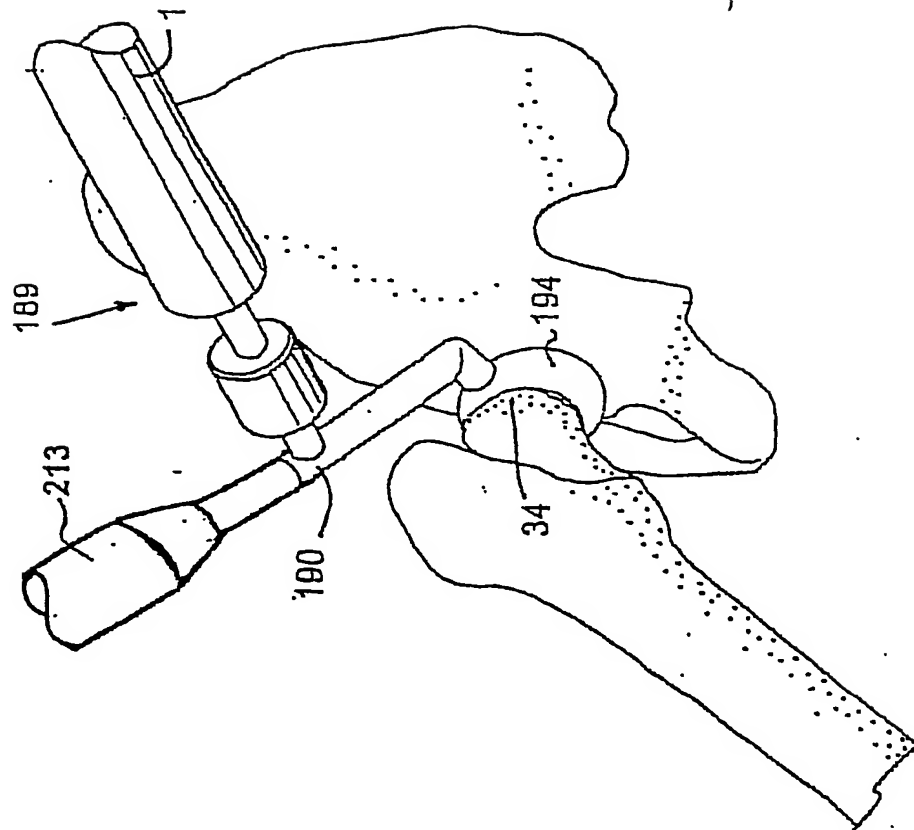


Fig. 21

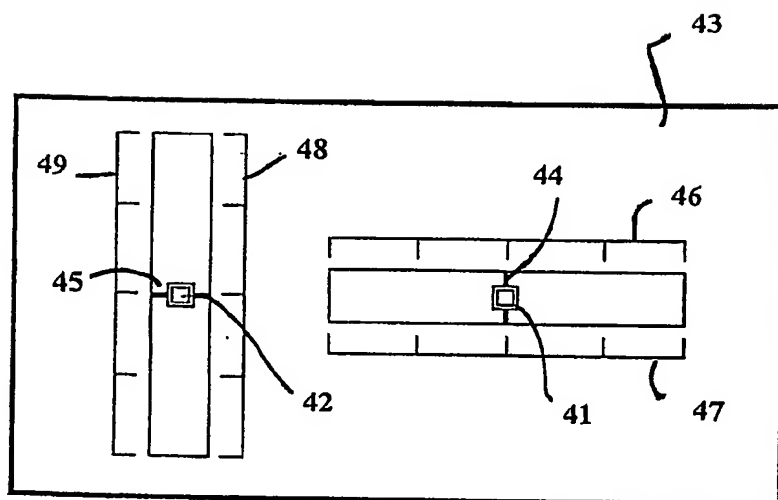


Fig. 22

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